

### REMARKS

Claims 1-50 and 52-63 are pending in the current application. Claim 51 has been cancelled. Claims 6, 50 and 59 have been amended to correct inadvertent clerical mistakes. No new matter is added.

Applicants' representative appreciates Examiner Liu's return call on April 14<sup>th</sup> in which he clarified that the Restriction Requirement mailed on November 14, 2007 has been withdrawn and a new Restriction Requirement mailed on March 21, 2008 has been issued.

### ELECTION/RESTRICTION

A requirement for restriction has been made under 37 C.F.R. 1.499 between the inventions of Groups:

1. Claims 1-20 and 37-51, drawn to a mutated FrpB protein and refolded FrpB protein and the pharmaceutical composition comprising the protein, and use of the protein thereof to prepare a medicament.
2. Claims 21-24, drawn to a polynucleotide encoding the protein, an expression vector comprising the polynucleotide, a host cell comprising the vector, and a method of producing said protein comprising culturing said host cell and recovering the expressed protein.
3. Claims 25-35 and 36, drawn to a method of refolding an FrpB protein comprising contacting the FrpB protein with an alkaline refolding buffer, and the buffer thereof (claim 36).
4. Claims 52-55, drawn to a process of using the FrpB protein for treating Neisserial infection.
5. Claims 56-57, drawn to an antibody for the FrpB protein and a pharmaceutical composition comprising antibody, and use of the antibody.
6. Claims 58-60, drawn to use of the antibody in manufacturing a medicament and for treating or preventing Neisserial infection/disease.

7. Claims 61-63, drawn to a method of diagnosing a Neisserial infection comprising identifying the FrpB protein within a biological sample from animal suspected of having said infection.
8. Claims 61-63, drawn to a method of diagnosing a Neisserial infection comprising identifying the antibody within a biological sample from animal suspected of having said infection.

Applicants respectfully request modification of the requirement for restriction, as provided by 37 CFR § 1.143. Applicants propose the following modifications to Groups 1 and 3 for consideration by the Examiner.

Group 1. Claims 1-20 and 38-50 (in part), drawn to a mutated FrpB protein and a pharmaceutical composition comprising the mutated protein. [removing (i) the refolded protein of Claim 37 and (ii) pharmaceutical composition of Claims 38-50 (in part) in so much as they depend from Claim 37].

Group 3. Claims 25-35, 36, 37 and 38-50 (in part) drawn to a method of refolding an FrpB protein comprising contacting the FrpB protein with an alkaline refolding buffer, the buffer thereof, and (i) the refolded FrpB protein of Claim 37, made by the method of Claim 25, and (ii) the pharmaceutical compositions of Claims 38-50 that depend from Claim 37.

Applicants provisionally elect Group 3 (Claims 25-35 and 36) with traverse.

Examiner's Group 3 is drawn to a method of refolding an FrpB protein comprising contacting the FrpB protein with an alkaline refolding buffer, and the buffer thereof. Applicants respectfully submit that PCT Rule 13 permits combinations of different categories of claims, specifically claims to a product, a process for making the product and a use for the product. M.P.E.P. § 1850 III(A). Claim 37 represents a product. Independent Claim 25, and dependent Claims 26-35, represent a process for making the product. Claims 38-50 (in so much as they depend directly or indirectly from Claim 37), represent a use of the product. Applicants respectfully submit that Claims 37 and 38-50 (in part) are a permissible combination

of different categories of claims under PCT Rule 13 and request rejoinder of these claims with Group 3.

#### **Additional Election Under 35 USC 121**

If Group 1 is elected, Applicants are required to elect one adhesin protein, or one Neisserial toxin protein, or one Neisserial Fe acquisition protein, or one Neisserial autotransporter, or one Neisserial membrane associated protein from Claim 48.

Applicants have not elected Group 1. Applicants have provisionally elected Group 3 and requested rejoinder of Claims 37 and 38-50 (in part).

Applicants submit that Claim 48, a pharmaceutical composition that contains a protein as provided in Claim 38, to which at least one additional Neisserial antigen has been added, is an embodiment of the same generic invention. Accordingly, Applicants respectfully request that, rather than subjecting embodiments containing an FrpB protein and another Neisserial antigen to a restriction requirement, these embodiments should be subjected to a species election. As previously submitted in our reply on December 14, 2007, page 4, Applicants would accede to an election of species without traverse, and elect the species of a pharmaceutical composition comprising a refolded FrpB protein without additional antigen, should the Examiner modify Group 3 to include Claims 37 and 38-50 (in part) and subject the additional Neisserial antigen embodiments to a species election.

#### **Species election**

If Group 1 is elected, Applicants are also required to further elect one species, i.e., one polysaccharide or oligosaccharide from a bacterial strain in Claim 50.

Applicants have not elected Group 1. However, if the Examiner modifies Group 3 to include Claim 50, as it depends indirectly from Claim 37, Applicants elect *Neisseria meningitidis* serotype C for initial examination on the merits. In the event that a generic claim is found allowable, Applicants understand that additional species which depend from and otherwise include all the limitations of the generic claims will be considered as provided by 37 CFR § 1.141.

**CONCLUSION**

Applicants provisionally elect Group 3 (Claims 25-35 and 36) with traverse. Applicants respectfully request modification of the Restriction Requirement under 37 CFR § 1.143. Applicants request modification of Group 3 to include Claims 37 and 38-50 (in part) and request that the additional embodiment containing a refolded FrpB protein and another Neisserial antigen (Claim 48) be subjected to a species election rather than a restriction requirement.

Applicants expressly reserve the right to prosecute the subject matter in the non-elected claims, originally filed claims, or any other claims supported by the specification in one or more continuing applications.

If the Examiner would like to discuss Applicants' request, the Examiner is encouraged to contact Applicants' undersigned representative.

Respectfully submitted:



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